REMARKS

In response to the office action mailed April 27, 2004, applicants submit the foregoing amendments to the claims and the following comments. Claims 17-27 are pending in the application. Applicants have amended claims 20, 21, 23, 24, 26, and 27. Reconsideration of the application is respectfully requested.

Objections to Claims 21 and 24

The examiner objected to claims 21 ands 24. The examiner asserted that the limitation of "outer diameter of 0.349 inches" is not commensurate in scope with the specification and suggested inserting –approximately-- before "0.349" in both claims 21 and 24. Applicants have amended claims 21 and 24 pursuant to the examiner's suggestion. Applicants respectfully submit that the objection to claims 21 and 24 should be withdrawn.

Claim Rejection Under 35 U.S.C. 101

The examiner rejected claim 26 under 35 U.S.C. 101 as allegedly being directed to non-statutory subject matter. The examiner asserted that claim 26 is improper because the outer surface is claimed as sealing with an interior of a body passageway. Pursuant to the examiner's suggestion, applicants have amended claim 26 to change "seals" with --is configured to seal--. Applicants respectfully submit that the rejection under 35 U.S.C. 101 has been overcome.

Claim Rejections under 35 U.S.C. 103

The examiner rejected claims 16-27 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,957,949 to Leonhardt in view of U.S. Patent No. 5,411,552 to Andersen.

Claims 16-19

The examiner alleges that "Leonhardt discloses an obstructing member (valve stent) with all the elements of claims 16, 17, 18, and 19, but is silent as to the obstructing member having an outer dimension sized to make continuous contact with

and seal with a bronchial sub-branch." The examiner further alleged that it would be obvious in view of Andersen to re-size the valve stent of Leonhardt for use in a bronchial sub-branch. According to the examiner, the Leonhardt device can be used in a bronchial sub-branch to "make continuous contact with and seal the inner dimension of the bronchial sub-branch, thereby enabling and resulting in all the required functional limitations."

The examiner is incorrect that the Leonhardt device, if re-dimensioned and placed in a bronchial sub-branch, would enable and result in all the functional limitations of claims 17-19. To the contrary, the Leonhardt device, if redimensioned pursuant to Andersen and placed in a bronchial sub-branch, would fail to result in several limitations recited in claims 17-19. For example, the Leonhardt device would fail to preclude inhaled air from flowing into the lung portion and would fail to collapse the lung and reduce the size of the lung. The Leonhardt device is unsuited for placement in the lung as its construction provides several air leak paths that would prevent the device from blocking air flow through a bronchial sub-branch, as described in the accompanying declaration of Declaration Of James I. Fann, M.D. Under 37 C.F.R. §1.132 (the "Fann Declaration"), attached hereto. As described in Dr. Fann's *curriculum vitae* (Exhibit 1 of Fann Declaration), Dr. Fann has extensive experience in the field of artificial valves for both cardiac and endobronchial use.

The graft material that surrounds the Leonhardt valve stent is made of a porous material, which provides a source of leak paths. Although Leonhardt states that the graft material has a "low" porosity, any porosity at all will result in air leakage across the device if placed in a lung. (Fann Declaration, ¶6.) Moreover, the Leonhardt valve stent includes sutures that are stitched between the graft and the frame to secure the graft to the frame. Such stitches create holes in the graft that form additional leak paths through which air can flow across the device. (Fann Declaration, ¶7.) Furthermore, Leonhardt teaches that the graft material is a "woven fabric". By definition, a woven fabric is formed of interweaved threads. Thus, a woven fabric inherently includes holes

between the thread weaves in the fabric, which would result in additional leak paths across the device if it were placed in a bronchial sub-branch. (Fann Declaration, ¶6.)

Such leak paths would provide a passageway for air to flow across the Leonhardt device if it were positioned in a bronchial sub-branch. Because the device would leak air, it would fail to preclude air from flowing into the lung portion and air would, therefore, continue to flow into the lung. Consequently, the lung would not reduce in size and would not collapse. (Fann Declaration, ¶5.) Thus, contrary to the examiner's position, the Leonhardt device, if re-sized and placed in a lung, would not result in all of the functional limitations recited in claims 16-19.

Moreover, there is no suggestion or motivation to change the Leonhardt valve to overcome its deficiencies with respect to usage in a bronchial sub-branch. Leonhardt makes no mention at all of being used in a lung environment and makes no suggestion of materials or construction that would motivate one of skill in the art to use the device in a lung environment. Consequently, applicants respectfully submit that the rejection of claims 16-19 should be withdrawn.

Claims 20-27

Independent claims 20, 23, 26, and 27 all include the limitation of a frame coupled to the valve, wherein the frame self-expands within a pulmonic passageway sufficiently to anchor the flow control device within the pulmonic passageway. Leonhardt and Andersen, both alone and in combination, fail to teach or suggest such a feature.

Leonhardt describes a valve stent 20 comprised of three elements, including a stent 26, a biological valve 22, and graft material 24. Leonhardt's stent 26 is self-expanding. See Leonhardt, col. 5, line 47. However, when the valve stent 20 is deployed in a body passageway, the stent 26 does not self-expand sufficiently to anchor the valve stent 20 in the passageway. Rather, Leonhardt requires that an expansion balloon 154 be used to anchor the valve stent in the body passageway. As stated in Leonhardt, after the valve stent is positioned in the body passageway, "[e]xpansion

balloon 154 is then inflated to a pressure sufficient to hold the distal end of valve stent 20 secure against the living tissue as seen in FIG. 9C. This ensures proper placement is maintained during the remainder of the deployment procedure and allows valve stent to mold itself quickly into the living tissue at the placement site and achieve a patent seal." (See Leonhardt, col. 11, lines 3-9.) Leonhardt provides no teaching or suggestion of a device that self-expands sufficiently to anchor in a body passageway.

Indeed, Leonardt teaches that the device is provided with a light-activated bioadhesive that is used to bind the Leonhardt device in place in a body passageway. The bioadhesive is directly located on the outside of the graft material or contained in photosensitive packets on the graft material. The adhesive is activated or released by exposing it to light of a proper frequency. As described in Leonhardt, after the device is placed in a body passageway using the expansion balloons, a "light emitting catheter capable of emitting light at the proper frequency to activate tissue bioadhesive 56 or packets 62 containing tissue bioadhesive 56 is inserted and energized. Bioadhesive 56 is exposed to the light sufficient to activate it ...."

Furthermore, Leonhardt et al. actually teaches away from using a frame that self-expands. Leonhardt openly states that self-expanding stents would not comply with the natural movement of the cardiovascular system (see col. 2, lines 64-66). That is apparently why Leonhardt et al. uses an expansion balloon 154 to seal the graft material 24 of the valve 20 to the wall of the biological passageway, because self-expanding stents would purportedly not work. See, for example, col. 2, lines 23-26, where Leonhardt et al. explains that cooled Nitenol, which is a self-expanding metal alloy, "does not exhibit sufficient force upon warming and reformation of its intended shape to maintain a seal between the stent and the tissue." So according to Leonhardt, self-expanding stents are not only too stiff to conform to the constant motion to which they would be exposed, but they do not exhibit enough force against biological passageways to maintain a seal between the stent and tissue. Thus, Leonhardt teaches away from using self-expanding stents or frames to seal against biological

passageways, and one of ordinary skill in the art would not have been led by Leonhardt et al. to use self-expanding stents or frames to seal against biological passageways.

Andersen also fails to teach or suggest a flow control device that self-expands sufficiently to anchor in a body passageway. Andersen describes a valve prosthesis for implantation in the body. Unlike the method recited in claim 25, deployment of the Andersen valve prosthesis requires the use of an expansion balloon 13 to expand the prosthesis sufficient to anchor the prosthesis in a body passageway. (See Andersen, col. 6, lines 20-44, FIGS. 5-7.) Although Andersen describes an embodiment of the valve prosthesis that self-expands (see col. 7, lines 17-23), Andersen makes no mention of the valve prosthesis self-expanding sufficiently to anchor in the body passageway.

In view of the foregoing, applicants respectfully submit that the rejection of claims 20, 23, 26, and 27 under 35 U.S.C. §103(a) should be withdrawn. Claims 21-22 and 24-45 depend from claim 20 and 23, respectively, and all of these claims recite subject matter that is neither taught nor suggested by the cited art. In addition, these claims are patentable in view of their dependence on claims 20 and 23

Double Patenting Rejections

The examiner rejected claims 16-22 and 26 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,954,766 in view of Andersen and over claims 1 and 7 of U.S. Patent No. 6,632,243 in view of Andersen.

Applicants respectfully disagree. Regarding claims 17 and 19, these claims both recite a conduit configured to be passed down a trachea. Neither claim 1 of U.S. Patent No. 5,954,766 nor claims 1 and 7 of U.S. Patent No. 6,632,243 make any mention of such a conduit. Andersen also fails to provide any teaching regarding a conduit configured to be passed down a trachea. Accordingly, the double patenting rejection of claims 17 and 19 should be withdrawn.

Applicants further submit that neither claim 1 of U.S. Patent No. 5,954,766 nor claims 1 and 7 of U.S. Patent No. 6,632,243 make any mention of an obstruction device that seals a bronchial sub-branch upon placement in the bronchial sub-branch to preclude air from being inhaled into the lung portion for collapsing the portion of the lung and reducing the size of the lung, as in claims 16 and 18 of the instant application. Andersen makes no mention whatsoever of use in the lung and, therefore, fails to provide the missing teaching. Accordingly, the double patenting rejection of claims 16 and 18 should be withdrawn.

Claim 20 recites a one-way valve dimensioned for pulmonary placement, wherein the valve is configured to restrict fluid flow and a frame coupled to the valve, wherein the frame self-expands within a pulmonic passageway sufficiently to anchor the flow control device within the pulmonic passageway. Neither the combination of claim 1 of U.S. Patent No. 5,954,766 with Andersen nor claims 1 and 7 of U.S. Patent No. 6,632,243 with Andersen results in all of the limitations of claim 20. Consequently, the double patenting rejection of claim 20 and its dependent claims should be withdrawn.

Applicants respectfully submit that all claims should be found patentable to the applicants, and an interference should be declared with U.S. Patent No. 6,293,951. If the Examiner has any questions regarding the foregoing, she is cordially invited to contact the undersigned so that any such matters may be promptly resolved.

Respectfully submitted,

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